NFPA
The Food Safety People

NATIONAL FOOD PROCESSORS ASSOCIATION

John R. Cady
President and Chief Executive Officer

1350 I Street, NW
Suite 300
Washington, DC 20005
202-639-5917
Fax: 202-637-8464

WASHINGTON, DC
DUBLIN, CA
SEATTLE, WA

December 24, 2003

VIA Email

Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: Docket No. 02N-0276. Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.
(68 Federal Register 58894; October 10, 2003)

Dear Sir or Madam:

The National Food Processors Association (NFPA) submits these comments on the interim final rule cited above.

NFPA is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international Members. NFPA Members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

Summary of Comments

NFPA supports efforts to ensure the security of the food supply, and we endorse and advance activities that can strengthen food security. NFPA and its Members supported the development of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), and worked to perfect its provisions. NFPA shares FDA's interest in assuring the effective and efficient implementation of the Bioterrorism Act. NFPA continues to provide education and outreach to its Members on the requirements established by the facilities registration interim final rule, and we assist Members during the facilities registration process, which includes providing liaison between food companies and FDA as questions and implementation issues have surfaced.

NFPA commends FDA for its efforts to implement the facilities registration provisions of the Bioterrorism Act within a severely limited time frame. The interim

02N-0276

C243

final rules on facilities registration is significantly more reasonable and effective compared to the proposed rules. However, industry's limited experience to date with these interim final rules has revealed areas where FDA should clarify provisions and highlights the need for additional refinements as described in the following.

NFPA strongly urges FDA to focus resources and additional effort to providing prompt and clear answers to the many questions posed to the Agency as the industry seeks to comply with the rule. Significant uncertainty remains on many issues and many situations and circumstances faced by companies and facilities attempting to comply with the regulations are not addressed in the guidance provided to date. Clear interpretations from the Agency are essential in order to ensure industry compliance is effective and resources are appropriately allocated. NFPA, alone, has submitted many questions to FDA that reflect the uncertainties industry faces in attempting to apply the regulation to the diverse and broad range of facilities and activities subject to registration. Numerous gray areas in the facilities registration provisions have surfaced due to situations that were unanticipated in the proposed rule stage or that emerged as a result of the Interim Final Rule. FDA should make clear in preamble or guidance that a company will not be penalized by FDA when, despite making a good-faith effort to register, they make errors because of a lack of clear FDA interpretation of a challenging aspect of facilities registration.

Identification of Facilities/Activities Subject to Registration

Farms and Farm Activities

Questions posed to NFPA and subsequently to FDA demonstrate that the preamble discussion and interim rule provisions concerning farms and farm activities do not clearly address many of the diverse situations commonly found in current agricultural operations. Significant uncertainty remains in determining when a "farm" is subject to an exemption from registration and under what circumstances the "farm" or another "facility" associated with crop or animal production must be registered. For example, there is mobile equipment used in crop harvesting that are used to perform what FDA might consider processing and packaging in that no further steps are taken to prepare the crop for sale to consumers. The mobile equipment has no fixed location, may be either owned or leased by the owner of the farm and may not be used for all crops grown on the farm or even in the same field. The use of the mobile equipment raises questions of whether it (the equipment) needs to be registered or whether its use on the farm voids the exemption that the farm might otherwise have. FDA's view is needed to determine if and how facility registration applies in this type of situation.

Another area of uncertainty is what constitutes "harvesting." Situations and practices brought to NFPA's attention demonstrate that classifying farm practices into discrete harvesting, processing, or holding steps is often not straightforward and can vary for different crops produced on the same farm, and, even, within the process and procedures used for the same crop. NFPA understands FDA's view is that activities on a farm determine whether that farm is exempt from facilities registration. However, FDA should

recognize that the guidance given to date does not give adequate guidance for determining, relative to what takes place within the confines of a farm field, when and if a farm is exempt from registration. NFPA urges FDA to respond directly to questions regarding farms and farm activities that have been submitted to date and to consider an approach that broadens the definition of harvesting to encompass what takes place in the field rather than in terms that identify activities such as washing and trimming.

Facilities that Hold or Manufacture/Process Food Incidental to Primary Business/Activity

There are numerous situations where business establishments and other facilities hold or prepare small quantities of food for business purposes. Following are some examples/situations.

Non-Food Retail Establishments that Provide Food Samples or Vending Machines

Many non-food retail establishments hold and distribute food products to consumers either directly or through vending machines as an incidental business practice. Food products may be provided to consumers for promotional purposes or as "treats," or as a service. Because food products are held and distributed, but not sold directly to consumers, it appears the retail food establishment exemption from registration does not apply. Similarly, the non-profit food establishment exemption does not apply.

Non-retail Establishments that Provide Complementary Food, Vending Machines, or Otherwise Hold/Distribute Food

Many non-retail establishments and facilities such as professional offices, administrative offices, and schools hold foods that are used in vending machines or are given directly to visitors, customers, or employees. Food manufacturing companies' administrative facilities, for example, frequently hold and provide visitors samples of their food products. Again, the exemptions provided in the interim final rule do not appear to apply in these situations.

Nonprofit Organizations

While the Final Interim Rule exempts "nonprofit food establishments" from registration, there are many non-profit organizations that hold, distribute, or prepare food. For example, a church may conduct a consumer test with a food company on church property as a fundraiser. A youth group may use a church kitchen to make holiday cookies that local businesses in turn sell as a fundraiser. It does not appear that the non-profit food establishment exemption applies to non-profit organizations and facilities that may hold, manufacture, or distribute food as an incidental activity.

Facilities Used by Nonprofit Organizations

Many nonprofit organizations meet in facilities that are donated or rented from other businesses. A soccer organization may meet in the basement of a bank once every two months. A scout organization may meet at an insurance company one night each week. A professional standards organization may meet twice annually in hotels. There are cases involving these situations where the nonprofit organization hosts consumer food research for fundraising, provides food samples/food door prizes to its members, or prepares food at a site. It is not clear what, if any, responsibility the host facility has for registering.

Facilities that Conduct Consumer Research

Many facilities around the country have been developed to conduct consumer evaluations among a small number of subjects, usually focus groups of eight to twelve consumers. These consumer group tests may involve tasting a food product and almost always involve providing food refreshments. In many respects these focus group sites are similar to restaurants or retailers with the exception that food is not sold. However, the registration requirement appears to apply to these facilities.

FDA has clearly and appropriately responded to issues previously raised regarding the scope of the registration requirements by exempting private residences and transport vehicles and refining the exemptions for retail food establishments, restaurants, and non-profit retail establishments. However, the broad interpretation of the Bioterrorism Act FDA has used and the specific provisions of the interim final rule continue to encompass a potentially huge number of facilities that will likely never be aware of their legal obligation or, if registered, make a meaningful contribution to achieving the purposes intended by Congress. In many respects, there appears to be little difference between the activities of restaurants, retail food establishments, and non-profit food establishments and those of the facilities described above. Also, FDA does not appear to have considered the potentially millions of establishments and facilities in the United States represented by the above examples in the regulatory analysis performed for the interim final rule. NFPA strongly suggests that FDA amend the registration provisions to exempt from registration facilities that only incidentally manufacture/process, pack, or hold food in their businesses/activities or that are functionally equivalent to facilities currently exempted. NFPA notes that the approaches used for determining the exemption status of retail food establishments and transport vehicles may have applicability to some of the examples given above.

Registration Provisions

Emergency Contact Number

Several issues have emerged with the details of the emergency contact telephone number. First, the FDA Interim Final Rule would require a registrant to develop and maintain a

24-hour emergency contact system that conforms to a uniform approach: having a single telephone number that connects to a live person 24 hours a day. NFPA interprets this requirement to mean a registrant may be required to hire a 24-hour answering or security service, or to have a satellite cellular phone that would never be out of range. Thus, the Interim Final Rule may impose costs on companies that were not described or quantified in either the Preliminary Regulatory Impact Analysis or the final Regulatory Impact Analysis on facility registration. FDA should estimate for the final rule the costs of maintaining a particular type of emergency contact system as set by the interim final rule emergency contact provision.

NFPA suggests the final rule permit lower cost alternatives to maintaining a 24-hour emergency contact system. In comments on the proposed rule, NFPA requested flexibility for the emergency contact system, so companies would be able to use existing systems. What FDA permitted for the Interim Final Rule was a system that was appropriately depersonalized, compared to the proposal, in that it does not require an individual name, but it is in fact not more flexible.. If FDA were to accommodate additional telephone numbers in the emergency contact section of the facility registration form, this would introduce needed flexibility into emergency contact operations. For example, some companies may have an emergency contact chain for use by local officials that includes a prioritized telephone list of several phone numbers for a facility that can be contacted in the event of emergency. This may include personnel at other locations, such as corporate headquarters. FDA could accommodate this emergency contact structure by allowing multiple telephone numbers in the emergency contact section of the facility registration form. Some emergency contact systems may also use pager numbers to contact a person with emergency responsibility for a facility. In the event of emergency the pager is activated and the responsible person can return the call immediately. Pagers are commonly and successfully used in emergency response situations, such as community fire services and physicians on call in hospitals. FDA should accommodate a multiplicity of options that would allow companies to integrate their emergency contact systems into FDA facility registration requirements without assuming additional costs. NFPA also urges FDA to recognize that a responsible person may not be immediately available and that response within a reasonable time, given that an emergency situation may exist, is acceptable.

Food Product Category Information

Some questions have emerged with respect to food product categories that must be reported in facility registration. NFPA urges FDA to clarify that the food product category information includes not only processed foods and finished products held at a facility, but also incoming ingredients and additives that are held because they are used in the processing of food. While we understand that food ingredients used in the preparation of food products are encompassed in the definition of "food" in the FFDCA, some food companies have had questions concerning the need to identify the food product categories of ingredients that they hold to prepare finished food products.

By way of example, a facility might produce products in one product category, Cakes and Pies - Bakery Products, Dough Mixes or Icings. A facility that produces such products might reasonably hold ingredients in all of the following categories:

- Bakery products, dough mixes or icings
- Whole grains, miller grain products (flours) or starch
- Food sweeteners (nutritive)
- Shell eggs and egg products
- Fruits and fruit products
- Vegetables and vegetable products
- Cheese and cheese products
- Gelatin, rennet, pudding mixes, pie fillings
- Milk, butter, or dried milk products
- Spices, flavors, and salts
- Chocolate and cocoa products
- Nut and edible seed products
- Color additives for foods
- Food additives /GRAS/other ingredients

Thus the facility processes one category but holds ingredients in fourteen categories. NFPA requests that FDA clarify in the final rule preamble, and in instructions to the facilities registration forms, whether the food product categories for such ingredients must be identified. While NFPA interprets FDA's response to comment 188 in the interim final rule preamble to specify that ingredients must also be reported, we believe that this requirement needs to be explained more clearly.

Confirmation of Registration

When a registrant completes the registration on-line, the system generates a confirmation and receipt that includes the facility's registration number and PIN. It is not made clear to the registrant that they should maintain security of the PIN at all times, and that they must be circumspect in releasing the registration number to other interested parties. FDA should make clear to registrants that the PIN is a security measure and should not be disclosed outside the company's authorized personnel, and that is not a regulatory requirement for companies to share registration numbers in ordinary commerce. The sharing of registration numbers by regulation only applies with respect to the requirements of the prior notice of imported foods.

In many cases, customers of registrants have been requesting that registration numbers be provided to confirm compliance with the registration requirements. NFPA urges FDA to make design changes to the registration confirmation that will allow its use in responding to customer demands for substantiation of compliance. FDA could issue an added page to the registration confirmation that includes the FDA name and logo, and identify the registered facility without the PIN or registration number. This FDA confirmation "page" could be used to indicate that the facility has been duly registered.

NFPA has attempted to educate its Members about their obligations for facility registration, including the aspect of sharing registration numbers with the trade. NFPA appreciates that FDA will keep this data confidential. Except for prior notice of imports, it is the registrant's option whether to share registration number. FDA should urge companies to consider their risks if they do not keep their registration numbers secure.

Technical Issues

NFPA urges FDA to create system quality controls and redundancies to ensure the contiguous, smooth operation of the facility registration electronic system. A system that purports to be available 24 hours a day, seven days a week should be available and operational all of that time. System downtime should be minimized by use of system redundancies or procedures where the system may be tested or maintained without falling off-line. NFPA also recommends periodic system audits, to ensure that the requirements of the electronic system data entry match precisely the requirements of the regulations. Such a regular audit practice might have prevented a software glitch that occurred about ten weeks into the facility registration process. In the period immediately following system maintenance, the electronic registration required the name of an individual in the emergency contact section even though the regulations do not require an individual's name. There should be a perfect match in requirements, and this should be subject to appropriate quality control measures.

Fields need to be designed to accept appropriate input. For example, the answer to the "secret question" in account management requires input of at least eight characters to be recognized by the system. Entries may have fewer than eight characters – even the example in FDA's tutorial uses fewer than eight characters. The system should recognize all inputs as valid.

NFPA recommends that FDA confirm that non-US foreign telephone numbers, such as those used in Canada and Mexico, are structured in the facility registration form to be recognized the same as a US telephone number. Non-US North American numbers use the same architecture as the US telephone system, and do not use country codes when calling among North American countries and to the United States. Likewise, a call originating in the United States going to Canada uses an area code and seven-digit telephone number, not a country code. The electronic registration system architecture must accommodate this reality.

These are just a few examples of the technical problems that have been reported to NFPA by Members as they register their facilities. NFPA recommends that FDA audit and edit to improve the technical functioning of the on-line registration system.

Associated Issues with Prior Notice

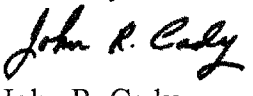
Questions have arisen regarding the need for registration numbers for the prior notice of foods for which a registration number cannot be obtained or is otherwise not available.

There are certain circumstances where US food companies may import into the United States small quantities of foods for research or testing purposes and there is no ability to report the facility registration number of the foreign manufacturer. This situation occurs because the foods shipped for research and testing purposes may be purchased in foreign countries at retail and the registration number of the manufacturer is not available and/or is not required. To solve this problem, FDA should either allow for the prior notice for this type of imported food to proceed without a registration number or preferably eliminate prior notice requirements completely.

A similar problem emerges for consumer-to-consumer shipments into the US of foods purchased at retail in foreign countries. These foods may not be available for purchase in the US and are shipped to a consumer in the US by a friend or relative in a foreign country. Such shipments could enter the US by international mail or air courier services. The facilities that produce the products in foreign country would not be required to register if they do not export to the US. Individual consumers in foreign countries should not be expected to seek out registration numbers of foreign facilitates that make the foods they want to send as gifts, nor should they be constrained against purchasing foreign manufactured food products for shipment as gifts. FDA should not require registration numbers for prior notice of imports of all foods sent as gifts between individuals.

Thank you for the opportunity to comment on this important issue. We stand ready to assist FDA in perfecting this rule.

Sincerely,



John R. Cady